

## REMARKS

### Restriction Requirement

In the Restriction Requirement that was mailed in this case on February 25, 2003, the Examiner required Applicants to elect one of the following two groups of claims:

I. Claims 5, 6, and 8-15<sup>1</sup>, drawn to a vector and a cell carrying the vector, classified in class 435, subclass 320.1.

II. Claim 17, drawn to a kit comprising a vector and a ligand, classified in class 514, subclass 1.

### Election

Applicants provisionally elect the invention of Group I, claims 5, 6, and 8-15, with traverse.

### Request for Reconsideration

Applicants submit that Groups I and II should be examined together.

In support of the above claim division, the Examiner asserts that the inventions of Groups I and II are patentably distinct because they "are chemically, biologically, and functionally distinct from each other." This is incorrect. These groups are not

---

<sup>1</sup> The Restriction Requirement actually refers to claims "5, 6, and -15." Based on the description of Group I, Applicants submit that this group should include claims 5, 6, and 8-15.

independent and distinct. Each is related and restriction is improper.

### *Procedure*

Applicants note that the present application is a divisional of a 35 U.S.C. § 371 U.S. National Stage Application of PCT/JP97/00678. Thus, PCT Rules 13.1 and 13.2 should be applied to the present application. Applicants submit that the Examiner has erred by applying the U.S. restriction rules of “patentable distinction.” Hence, for this reason alone, the restriction requirement is fundamentally flawed.

### *Applying the PCT Rules*

Under PCT Rule 13.2, unity of invention exists when there is a technical relationship among the claimed inventions, involving one or more of the same or corresponding special technical features. The expression “special technical features” refers to those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Moreover, the administrative instructions regarding unity of invention state that unity of invention is considered only in relation to the independent claims. If the independent claims avoid the prior art and satisfy the requirements of unity of invention, no problem of lack of unity arises with respect to any claims that depend therefrom. In particular, it does not matter if a dependent claim itself contains a further invention. Equally no problem arises in cases of

a genus/species situation where the genus claims avoids the prior art. (See M.P.E.P. (Eighth Edition, August 2001) Administrative Instructions under the PCT, Annex B).

In this case, there are only two independent claims - claims 5 and 8. The “special technical features” shared by the claims are defined by the broader of the two claims, namely claim 5. As these special technical features define a contribution over the prior art, under the PCT Rules, claims 5 and 8, and their dependent claims (including dependent kit claim 17), satisfy the requirements of unity of invention and should be examined together in a single application.

#### *Applying the U.S. Rules*

Assuming, *arguendo*, that U.S. restriction rules are deemed proper in this case, the restriction is still flawed. As is noted above, the Examiner alleges that the products of Inventions I (vector and cell) and II (kit) are patentably distinct from each other because “they have distinct functional, chemical, and physical properties and are capable of separate use and manufacture.” This restriction is not proper as the inventions of Groups I and II are substantially related.

In particular, the vectors and cells of claims 5, 6, and 8-15 and the kit of claim 17 are related as sub-combination and combination. Applicants note that M.P.E.P. (Eighth Edition, August 2001) § 806.05(c) states that, “[w]here the relationship between claims is such that the separately claimed subcombination B<sub>sp</sub> constitutes the essential

distinguishing feature of the combination AB<sub>sp</sub> as claimed, the inventions are not distinct and a requirement for restriction must not be made, even though the subcombination has separate utility.” Herein, all the limitations of the subcombination claims (i.e., vectors of claims 5 and 8) are reiterated in the combination claim (i.e., the kit of claim 20).

Therefore, restriction between Groups I and II is in error.

In sum, whether viewed under PCT Rules or U.S. Rules, the present restriction is clearly flawed. Nevertheless, as noted above, in order to be responsive, Applicants have provisionally elected Group I for examination and respectfully request the Examiner to reconsider the restriction requirement and examine both groups in the present application.

#### Amendment

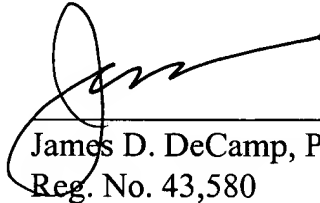
Claim 5 has been rewritten in independent form. Support for this amendment may be found, for example, in original claim 1 from which original claim 5 depended. No new matter is added by this amendment.

CONCLUSION

Applicants respectfully request reconsideration of the requirement for restriction. Enclosed is a Petition to extend the period for replying to the Restriction Requirement for four months, to and including July 25, 2003. Also enclosed is a check in payment of the required extension fee. If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 24 July 2003

  
\_\_\_\_\_  
James D. DeCamp, Ph.D.  
Reg. No. 43,580

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045